Applicant or Patentee: Joseph R. Berger Attorney's
Serial or Patent No.: 08/244,988 Docket No.: 44657-A-PCT-
Filed or Issued: Int'l Filing Date: 20 October 1993
Title of Invention or Patent: A METHOD FOR AMELIORATING MUSCLE WEAKNESS/WASTING IN A
PATIENT INFECTED WITH HUMAN IMMUNODEFICIENCY VIRUS-TYPE
VERIFIED STATEMENT (DECLARATION) CLAIMING
SMALL ENTITY STATUS UNDER 37 C.F.R. \$1.9(f)
AND §1.27(c) - SMALL BUSINESS CONCERN
I hereby declare that I am:
the owner of the small business concern identified below.
an official of the small business concern empowered to act on behalf of the concern identified below:
Constilled below.
Name of Concern: BTG Pharmaceuticals Corp.
Address of Concern: 70 Wood Avenue South  Iselin, New Jersey 08830
Iselin, New Jersey 00030
\$1.9(d), for purposes of paying reduced fees under 35 U.S.C. \$41(a) and \$41(b), in that the number of employees of the concern, including those of its affiliates, does not exceed five hundred (500) persons. For purposes of this verified statement, the number of employees of the business concern is the average number, over the previ us fiscal year, of the persons employed by the business concern on a full-time, part-time, or temporary basis during each pay period of the fiscal year, and concerns are affiliates of each other when, either directly or indirectly, one concern controls or has power to control the other, or a third party or parties controls or has power to control both.  I hereby declare that rights under contract or law have been conveyed to and remain
with the small business concern identified above with regard to the invention entitled
A METHOD FOR AMELIORATING MUSCLE WEAKNESS/WASTING IN A PATIENT INFECTED WITH HUMAN
described in: IMMUNODEFICIENCY VIRUS-TYPE 1
the specification filed herewith  X application serial no. 08/244,988 filed Int'l Filing Date: 20 October 1993 patent no. issued
If the rights held by the above identified small business concern are not exclusive, each individual, concern or organization having rights to the invention is listed below and no rights to the invention are held by any person, other than the inventor, who could not qualify as an independent inventor under 37 C.F.R. \$1.9(c)*, any concern which could not qualify as a small business concern under 37 C.F.R. \$1.9(d)* or as a nonprofit organization under 37 C.F.R. \$1.9(e)*.
Jame:
ddress:
Individual Small Business Concern Nonprofit Organization

anome: Separate verified statements are required for each named person, concern, or organization having rights to the invention averring to their status as small entities. 37 C.F.R. §1.27.

- (c) An independent inventor as used in this chapter means any invent r who (1) has not assigned, granted, conveyed, or licensed, and (2) is under no obligation under contract or law to assign, grant, convey, or license, any rights in the invention to any person who could not likewise be classified as an independent inventor if that person had made the invention, or to any concern which would not qualify as a small business concern or a nonprofit organization under this section.
- (d) A small business concern as used in this chapter means any business concern as defined by the Small Business Administration in 13 C.F.R. §121.3-18, published n September 30, 1982 at 47 FR 43273. For the convenience of the users of these regulations, that definition states:
- §121.3-18 Definition of small business for paying reduced patent fees under Title 35, U.S. Code.
- (a) Pursuant to Pub. L. 97-247, a small business concern for purposes of paying reduced fees under 35 U.S. Code 41(a) and (b) to the Patent and Trademark Office means any business concern (1) whose number of employees, including those of its affiliates, does not exceed 500 persons and (2) which has not assigned, granted, conveyed, or licensed, and is under no obligation under contract or law to assign, grant, convey or license, any rights in the invention to any person who could not be classified as an independent inventor if that person had made the invention, or to any concern which would not qualify as a small business concern or a nonprofit organization under this section. For the purpose of this section concerns are affiliates of each other when either, directly or indirectly, one concern controls or has the power to control the other, or a third party or parties controls or has the power to control both. The number of employees of the business concern is the averag over the fiscal year of the the persons employed during each of the pay periods of the fiscal year. Employees are those persons employed on a full-time, part-time or temporary basis during the previous fiscal year of the concern.
- (b) If the Patent and Trademark Office determines that a concern is not eligible as a small business concern within this section, the concern shall have a right to appeal that determination to the Small Business Administration. The Patent and Trademark Office shall transmit its written decision and the pertinent size determination file to the SBA in the event of such adverse determination and size appeal. Such appeals by concerns should be submitted to the SBA at 1441 L Street, NW., Washington, D.C. 20416 (Attention: SBA Office of General Counsel). The appeal should state the basis upon which it is claimed that the Patent and Trademark Office initial size determination on the concern was in error; and the facts and arguments supporting the concern's claimed status as a small business concern under this section.
- (e) A nonprofit organization as used in this chapter means (1) a university or other institution of higher education located in any country; (2) an organization of the type described in section 501(c)(3) of the Internal Revenue Code of 1954 (26 U.S.C. 501(c)(3)) and exempt from taxation under section 501(a) of the Internal Revenue Code (26 U.S.C. 501(a)); (3) any nonprofit scientific or educational organization qualified under a nonprofit organization statute of a state of this country (35 U.S.C. 201(i)); or (4) any nonprofit organization located in a foreign country which would qualify as a nonprofit organization under paragraphs (e)(2) or (3) of this section if it were located in this country.

Small Entity/Small Business Concern Page -2-

I acknowledge the duty to file, in this application or patent, notification of any change in status resulting in loss of entitlement to small entity status pri r t paying, or at the time of paying, the earliest of the issue fee or any maintenance fee due after the date on which status as a small entity is no longer appropriate. 37 C.F.R. §1.28(b)\*.

I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under 18 U.S.C. \$1001, and that such willful false statements may jeopardize the validity of the application, any patent issuing thereon, or any patent to which this verified statement is directed.

Name of Person Signing:	Sim Fass, Ph.D.	
Title In Organization:	President	
Address:	70 Wood Avenue South	
	Iselin, New Jersey 08830	
	~ 11/	
Date Of Signature:	9/10/95	
	1777	



## Beclaration and Power of Attorney

As a below-named inventor. I hereby declare that:

My residence, post office address, and citizenship are as stated below next to my name.

I believe I am the original, first and sole inventor (if only one name is listed below or an original, first and joint inventor (if plural names are listed below) of the subject matter which is claimed and for which a patent is sought on the invention entitled:

A METHOD FOR AMELIORATING MUSCLE WEAKNESS/WASTING IN A PATIENT INFECTED WITH HUMAN IMMUNODEFICIENCY VIRUS-TYPE 1

the specification ( (check one)	of which		
·	is attached hereto.		
	x was filed on October 20	0, 1993	a:
	Application Serial No. PCT/US9	3/10063 U.S. Ser	ial No. 08/244,988
·. ,	and was amended on	(if applicable)	
· ·	hat I have reviewed and undersi- uding the claims, as amended by ai	_	_
pecification, incli acknowledge the		ny amendment referre which I am aware wh	ed to above. Nich is material to the
pecification included acknowledge the examination of the section 1.56(a).  Thereby claim for foreign application elow any foreign	uding the claims, as amended by ai e duty to disclose information of	ny amendment referre which I am aware wh h Title 37. Code of 35. United States Coa ticate listed below and	ed to above.  The is material to the Federal Regulations  The Section 119 of any have also identified
pecification included acknowledge the examination of the section 1.56(a).  Thereby claim for foreign application elow any foreign	uding the claims, as amended by any duty to disclose information of this application in accordance with the priority benefits under Title in(s) for patent or inventor's certific application for patent or inventorial intention on which priority is claimed:	ny amendment referre which I am aware wh h Title 37. Code of 35. United States Coa ticate listed below and	ed to above.  The is material to the Federal Regulations  The Section 119 of any have also identified

(b) Once status as a small entity has been established in an application or patent, fees as a small entity may thereafter be paid in that application or patent without regard to a change in status until the issue fee is due or any maintenance fee is due. Notification of any change in status resulting in loss of entitlement to small entity status must be filed in the application or patent prior to paying, or at the time of paying, the earliest of the issue fee or any maintenance fee due after the date on which status as a small entity is no longer appropriate pursuant to \$1.9 of this part. The notification of change in status may be signed by the applicant, any person authorized to sign on behalf of the assignee, or an attorney or agent of record or acting in a representative capacity pursuant to \$1.34(a) of this part.

ΠJ

I hereby claim the benefit under Title 35. United States Code. Section 120 of any United States Application(s) listed below and, insofar as the subject matter of each of the claims of this application is not disclosed in the prior United States application in the manner provided by the first paragraph of Title 35. United States Code. Section 112. I acknowledge the unity to disclose material information as defined in Title 37, Code of Federal Regulations. Sections 1.56(a) which occurred between the filing date of the prior application and the national or PCT international filing date of this application:

Application Serial No.	Filing Date	Status
PCT/US93/10063	October 20, 1993	
		···
	<del></del>	

## And I hereby appoint

John P. White (Reg. No. 28,678); Norman H. Zivin (Reg. No. 25,385); Thomas F. Moran (Reg. No. 16,579); Ivan S. Kavrukov (Reg. No. 25,161); Christopher C. Dunham (Reg. No. 30,141); Peter J. Phillips (Reg. No. 29,691); Richard S. Milner (Reg. No. 33,970); Matthew J. Golden (Reg. No. 35,161); Albert Wai-Kit Chan (Reg. No. 36,479); Matthew B. Tropper (Reg. No. 37,457); Levis J. Kreisler (Reg. No. 38,522); Robert T. Maldonado (Reg. No. 38,232).

and each of them. all c/o Cooper & Dunham LLP, 1185 Avenue of the Americas, New York, New York 10036, my attorneys, each with full power of substitution and revocation. to prosecute this application, to make alterations and amendments therein, to receive the patent. to transact all business in the Patent and Trademark Office connected therewith and to file any International Applications which are based thereon under the provisions of the Patent Cooperation Treaty.

Please address all communications, a	address all communications, and direct all telephone calls, regarding this application to	
John P. White	Reg. No. 28,678	
statements made on information an statements were made with the know are punishable by fine or imprisonm	made herein of my own knowledge are true and that all d belief are believed to be true; and further that these viedge that willful false statements and the like so made ent, or both, under Section 1001 of Title 18 of the United false statements may jeopardize the validity of the	
	. Berger (Sim Fass, on behalf of and as agent for)	
Inventor's signature  Citizenship United States of A	merica Date of signature 4/10/95	

Date of signature Citizenship 6460 S.W. 109th Street, Miami, Florida 33156 Residence Post Office Address University of Kentucky-Annex 4, Chambers Building, Room 228E Lexington, Kentucky 40536